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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,325	09/12/2005	Kevin Woehr	1131-14-PCT-PA-TD	5105

22145 7590 03/30/2009

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EXAMINER	
ANDERSON, MICHAEL J	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,325	WOEHR, KEVIN	
	Examiner	Art Unit	
	MICHAEL J. ANDERSON	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The references cited 12/23/2008 have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08 in compliance with 37 CFR 1.98(a)(1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bialecki (US 6,652,486) in view of Tauschinski (US 4,387,879).

With regards to claim 1, Bialecki discloses (figures 1-10) catheter insertion device comprising a hollow catheter hub (22) having a catheter tube (28, 31) attached at a distal end thereof, a needle hub (24) having a hollow needle (38) attached thereto and

extending through the catheter hub and the catheter tube when in a ready position (figure 1), a needle guard element (26) arranged displaceably on the needle in the catheter hub and having an engaging section (72, 98) which engages with an engaging means (44) formed near the needle tip when the hollow needle is removed from the catheter hub (figures 9 and 10). However, Bialecki does not disclose wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in, the ready position and which automatically closes after the removal of the needle, and wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube. Tauschinski discloses (figures 1-4) a check valve (7) for use in the distal end of a catheter hub (1). Therefore it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a self sealing valve to block fluid flow.

With regards to claim 2 Bialecki and Tauschinski disclose the device according to claim 1, and Tauschinski further discloses wherein the catheter hub comprises a distal hub element (6) and a proximal hub element (2), and the check valve is held between the distal hub element and the proximal hub element, which are joined to one another (figure 2).

With regards to claim 3, Bialecki and Tauschinski disclose the device according to claim 1 and Tauschinski further discloses wherein the check valve has a plurality of radially elastically expandable valve flaps (3, 8, figure 3) configured to be moved into an

open position by fluid pressure generated from a syringe (this would be inherent give enough fluid pressure).

With regards to claim 4, Bialecki and Tauschinski disclose the device according to claim 1 and Bialecki further discloses wherein the catheter hub comprises an inner circumference and a radial projection (34) projecting radially from the inner circumference which is configured to engage with the needle guard element in the ready position (figure 1).

With regards to claim 5, Bialecki and Tauschinski disclose the device according to claim 1 and Tauschinski further discloses wherein the check valve comprises a valve disc (3), which has radial slits (8) starting from a middle section of the valve disk and a valve actuating element (10) which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element.

With regards to claim 6, Bialecki and Tauschinski disclose the device according to claim 5 and Tauschinski further discloses wherein the valve actuating element is formed as a hollow cylinder (10) with a truncated cone-shaped distal end section and comprising two proximally extending legs (figure 3 shows the hollow cone shaped actuating element) defining the hollow space for receiving the needle guard therebetween.

With regards to claim 7, Bialecki and Tauschinski disclose the device according to claim 6 and Tauschinski further discloses wherein the hollow cylindrical valve actuating element comprises an inner circumference and a radial projection (column 3, lines 51-58).

With regards to claim 8, Bialecki and Tauschinski disclose the device according to claim 5 and Tauschinski further discloses wherein the valve actuating element has a truncated cone-shaped abutting section (figure 2, the cone tapers).

With regards to claim 9, Bialecki and Tauschinski disclose the device according to claim 1 and Bialecki further discloses wherein the needle guard element (26) is formed as a spring clip which has diametrically opposite spring arms (96 and 100) starting from a rear wall provided with a bore (72), wherein bent end sections (98 and 102) of the spring arms overlap and block the needle tip (figures 8 and 9) when the engaging means of the needle comes to abut on the rear wall.

With regards to claim 10, Bialecki and Tauschinski disclose the catheter insertion device comprising (as for the claims above, namely claims 1, 5 and 9): a catheter tube attached to an end of a catheter hub the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub and in mechanical communication with a movable valve actuating element for opening the valve, and wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter hub and the catheter hub; and a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve in a ready position.

With regards to claim 11, Bialecki and Tauschinski disclose the catheter insertion device comprising (as for the claims above, namely claims 1, 5 and 9): a catheter tube

attached to an end of a catheter hub. the catheter tube comprising a lumen and the catheter hub comprising an interior cavity; a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube and comprising an engaging section near a needle tip; a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening, and wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub; a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub; and wherein a valve actuating element is slidably displaced in the interior cavity of the catheter hub for opening the valve.

With regards to claim 12, Bialecki and Tauschinski disclose the device according to claim 10 and Bialecki further discloses (figure 8) wherein the two needle guard arms cross one another.

With regards to claim 13, Bialecki and Tauschinski disclose the device according to claim 10 and Bialecki further discloses wherein the needle guard element comprises a proximal wall comprising an opening (72) having the needle passing therethrough.

With regards to claim 14, Bialecki and Tauschinski disclose the device according to claim 10 and Tauschinski further discloses wherein tile valve is a disc having at least one slit (8) formed therein.

With regards to claim 15, Bialecki and Tauschinski disclose the device according to claim 10 and Tauschinski further discloses wherein the movable valve actuating

element comprises two leg sections (figures 2 and 3 the cone (10) is hollow) comprising a space therebetween for accommodating the needle guard.

With regards to claim 16, Bialecki and Tauschinski disclose the device according to claim 11 and Bialecki further discloses wherein the engaging section (44, figure 9) is crimp.

With regards to claim 17, Bialecki and Tauschinski disclose the device according to claim 11 and Bialecki further discloses wherein the needle guard further comprises at least one arm (88) comprising an apex abutting a shoulder located on the interior surface (34) of the catheter hub.

With regards to claim 18, Bialecki and Tauschinski disclose the device according to claim 11 and Bialecki further discloses wherein the needle guard comprises two arms (96 and 100) that intersect one another.

With regards to claim 19, Bialecki and Tauschinski disclose the device according to claim 11 and Tauschinski further discloses wherein the valve actuating element comprises two leg sections (figures 2 and 3 the cone (10) is hollow) comprising a space therebetween for accommodating the needle guard.

With regards to claim 20, Bialecki and Tauschinski disclose the device according to claim 11 and Bialecki further discloses wherein the needle guard is made from a metal material (column 4, lines 25-28).

With regards to claim 21, Bialecki and Tauschinski disclose the device according to claim 1 and Tauschinski further discloses it further comprising a valve actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section,

with two legs extending proximally therefrom, the two proximally extending legs (figures 2 and 3 the cone (10) is hollow) defining a space therebetween configured for receiving the needle guard element.

With regards to claim 22, Bialecki and Tauschinski disclose the device according to claim 21 and Tauschinski further discloses wherein the catheter hub comprises a diameter variation on an inner circumference of the catheter hub located between a distal end and a proximal end of the valve actuating element (figures 2 and 3).

With regards to claim 23, Bialecki and Tauschinski disclose the device according to claim 10 and Tauschinski further discloses wherein the movable valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs (figures 2 and 3 the cone (10) is hollow) defining a space therebetween configured to receive the needle guard element.

With regards to claim 24, Bialecki and Tauschinski disclose the device according to claim 10 and Tauschinski further discloses wherein the catheter hub comprises a diameter variation on an inner circumference of the catheter hub located between a distal end and a proximal end of the valve actuating element when in the ready position.

With regards to claim 25, Bialecki and Tauschinski disclose the device according to claim 11 and Tauschinski further discloses wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section, comprising two proximally extending legs (figures 2 and 3 the cone (10) is hollow) defining a space therebetween configured for receiving the needle guard element therebetween.

With regards to claim 26, Bialecki and Tauschinski disclose the device according to claim 11 and Tauschinski further discloses wherein the catheter hub comprises a diameter variation on an ironer circumference of the catheter hub located between a distal end and a proximal end of the valve actuating element when in the ready position.

Response to Amendment

The present communication responds to the Amendment of 12/23/2008. By this communication, claims 1, 5-7, 10-11, 15 and 19 were amended and new claims 21-26 were added. The amendments did not add new matter. Claims 1-26 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ANDERSON whose telephone number is (571)272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Anderson/

Examiner
Art Unit 3767

MJA
3/26/2009
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767